

WE CLAIM:

1 1. A stable pharmaceutical composition comprising a core, wherein the core
2 includes rabeprazole and at least 10% w/w of low viscosity hydroxypropylcellulose.

1 2. The stable pharmaceutical composition according to claim 1, wherein the core
2 further comprises an antioxidant.

1 3. The stable pharmaceutical composition according to claim 1, wherein the
2 viscosity of the low viscosity hydroxypropylcellulose ranges from about 5 m. Pas to about
3 300 m. Pas.

1 4. The stable pharmaceutical composition according to claim 3, wherein the
2 viscosity of the low viscosity hydroxypropylcellulose ranges from about 50 m. Pas to about
3 200 m. Pas.

1 5. The stable pharmaceutical composition according to claim 2, wherein
2 antioxidant comprises one or both of butylated hydroxy toluene and butylated hydroxy
3 anisole.

1 6. The stable pharmaceutical composition according to claim 5, wherein the
2 antioxidant comprises from about 0.02% to about 0.2% by weight of the total core weight.

1 7. The stable pharmaceutical composition according to claim 1, wherein the core
2 further comprise polyvinylpyrrolidone.

1 8. The stable pharmaceutical composition according to claim 7, wherein the
2 average molecular weight of the polyvinylpyrrolidone ranges from about 10,000 to about
3 360,000.

1 9. The stable pharmaceutical composition according to claim 8, wherein the
2 average molecular weight of polyvinylpyrrolidone ranges from about 40,000 to about 60,000.

1 10. The stable pharmaceutical composition according to claim 7, wherein the
2 polyvinylpyrrolidone comprises from about 0.5% to about 5% by weight of the total core
3 weight.

1 11. The stable pharmaceutical composition according to claims 1, wherein the core
2 is selected from the group consisting of tablet, granule and capsule.

1 12. The stable pharmaceutical composition according to claim 11 wherein the core
2 is a tablet.

1 13. The stable pharmaceutical composition according to claim 1, wherein the core
2 is coated with a subcoat layer and an enteric coat layer.

1 14. The stable pharmaceutical composition according to claim 13, wherein the
2 subcoat layer comprises one or more film forming agents.

1 15. The stable pharmaceutical composition according to claim 14, wherein the one
2 or more film forming agents comprises one or more of microcrystalline cellulose, carageenan,
3 ethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose,
4 carboxymethylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, polyethylene glycol,
5 polyvinyl alcohol and xanthan gum.

1 16. The stable pharmaceutical composition according to claim 15, wherein the
2 film-forming agent comprises hydroxypropyl methylcellulose.

1 17. The stable pharmaceutical composition according to claim 13 wherein the
2 subcoat layer includes an antioxidant.

1 18. The stable pharmaceutical composition according to claim 13, wherein the
2 enteric coat layer comprises one or more enteric polymers.

1 19. The stable pharmaceutical composition according to claim 18, wherein the
2 enteric polymer comprises one or more of cellulose acetate phthalate, hydroxypropyl
3 methylcellulose acetate phthalate, polyvinyl acetate phthalate, hydroxy propyl phthalate,
4 hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate;
5 and methacrylic acid copolymers.

1 20. The stable pharmaceutical composition according to claim 19, wherein the
2 enteric polymer comprises hydroxypropyl methylcellulose phthalate.

1 21. The stable pharmaceutical composition according to claim 13, wherein one or
2 more of the core, the subcoat layer, and the enteric layer further comprise pharmaceutically
3 acceptable inert excipients.

1 22. The stable pharmaceutical composition according to claim 21, wherein the one
2 or more pharmaceutically acceptable inert excipients are selected from the group consisting of
3 binders, disintegrants, lubricants, glidants, diluents, plasticizers, opacifiers, and coloring
4 agents.

1 23. A process for preparing a stable pharmaceutical composition comprising a
2 core, the process comprising:

3 preparing a core by

4 (i) blending rabeprazole and a low viscosity hydroxypropylcellulose to form a
5 blend, and

6 one or both of (ii) granulating the blend and (iii) compressing the blend to form
7 a compact mass core, wherein the low viscosity hydroxypropylcellulose comprises at
8 least 10% w/w of the core.

1 24. The process of claim 23, further comprising coating the core with one or both
2 of a subcoat layer and an enteric coat layer.

1 25. The process of claim 23, further comprising blending one or more antioxidants
2 with the rabeprazole and low viscosity hydroxypropylcellulose.

1 26. The process according to claim 25, wherein the antioxidant is adsorbed over a
2 diluent.

1 27. The process according to claim 23, wherein the core is selected from the group
2 consisting of tablet, granule and pellet.

1 28. The process according to claim 27, wherein the core comprises a tablet.

1 29. The process according to claim 23, wherein the core is prepared by one or
2 more of a wet granulation method, a dry granulation method, or a direct compression method.

1 30. The process according to claim 29, wherein the core is prepared by direct
2 compression method.

1 31. The process according to claim 24, wherein one or both of the subcoat layer
2 and the enteric coat layer are applied as a solution/suspension.

1 32. The process according to claim 31, wherein the solution/suspension is prepared
2 in solvents selected from the group consisting of methylene chloride, isopropyl alcohol,
3 acetone, methanol, ethanol, water and mixtures thereof.

1 33. The process according to claim 24, wherein one or both of the subcoat layer
2 and the enteric coat layer are applied using a hot melt technique.

1 34. The process according to claim 24, wherein one or more of the core, the
2 subcoat layer, and the enteric coat layer contains one or more pharmaceutically acceptable
3 inert excipients.

1 35. The process according to claim 34, wherein the one or more pharmaceutically
2 acceptable inert excipients is selected from the group consisting of binders, disintegrants,
3 lubricants, glidants, diluents, plasticizers, opacifiers, and coloring agents.

1 36. The process according to claim 24, wherein the viscosity of the low viscosity
2 hydroxypropylcellulose ranges from about 5 m. Pas to about 300 m. Pas.

1 37. A method of treating digestive ulcers in a mammal by administering to the
2 mammal a stable pharmaceutical composition of rabeprazole, wherein the composition
3 includes a core comprises rabeprazole and at least 10% w/w of low viscosity hydroxypropyl
4 cellulose.

1 38. The method of treating of claim 37, wherein the viscosity of the low viscosity
2 hydroxypropylcellulose ranges from about 5 m. Pas to about 300 m. Pas.

1 39. The method of treating of claim 37, wherein the core further comprises an
2 antioxidant.